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WO 95/06496 A1 US 5466465 A US 4067342 A

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(54) **Patch structures for transdermal therapy**

(57) A patch structure 10 for transdermal therapy comprises a layer of sheet material 11 carrying copper particles 12 on or embedded in an adhesive pad 13 of foam or an elastomeric material. This may be in a ring formation about a zinc coated rare earth magnet 14. Alternatively there may be copper and zinc particles. Sheet material 11 carries a further layer 15 of adhesive for application to the skin. In use, very small electromagnetic impulses are generated which are particularly useful in the treatment of skeletal or muscular pain. The particulate material may also be a different metal, ceramic, gelatinous, soluble plastic, natural sponge or cellulose or any combination thereof. The particles may be spherical, cylindrical, hollow, solid or porous and may carry an active ingredient for therapy.

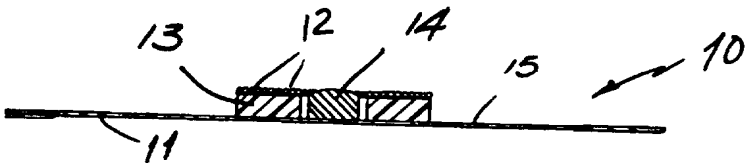

FIG. 2

GB 2 307 862 A

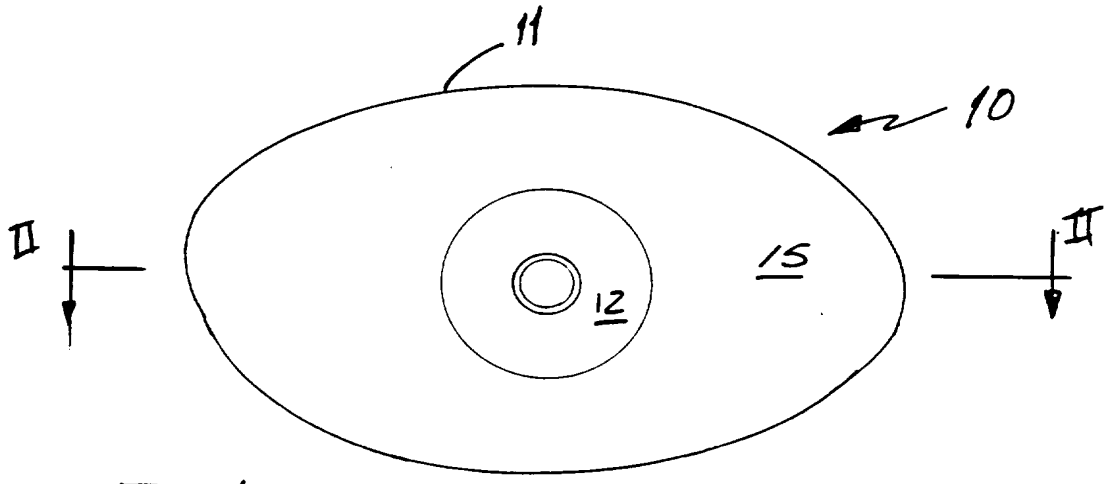

FIG. 1

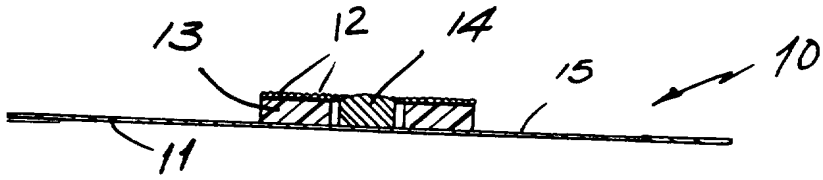

FIG. 2

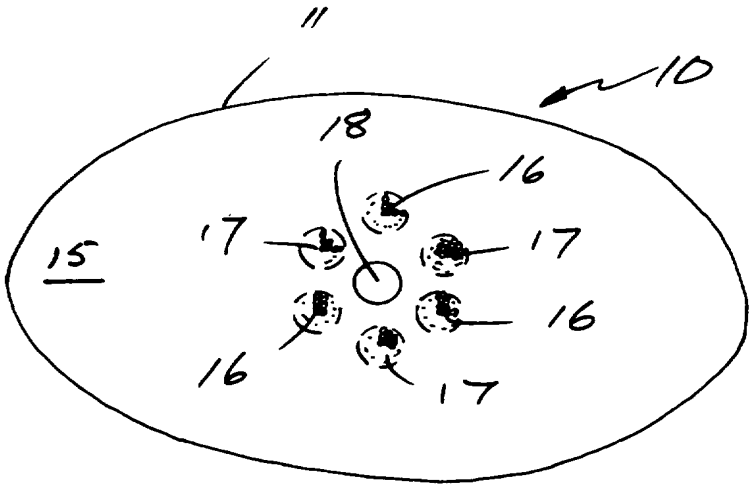

FIG. 3

PATCH STRUCTURES FOR TRANSDERMAL THERAPY

This invention relates to patch structures for transdermal therapy.

Patches are well known for providing treatment of varying effects directly through or on the skin. The most well known being the nicotine patch and hormone replacement patches. Other examples include patches containing metallic sheet material, such as copper (as disclosed in *WO95/09591*) or magnetic therapy (as disclosed in GB Patent *1596314*). Existing patches have a number of disadvantages. Nicotine patches and the like tend to release their active ingredients relatively quickly and thus it is not easy to maintain either a controlled dose, or a slow release. Also in some patches the active ingredients are in powder form and can be partially or totally covered by the adhesive used to adhere them to the patch, thereby restricting their effect.

In other cases, such as simple dressings the active ingredients may be applied in liquid form and these tend to dry in an uncontrolled manner. Patches incorporating metallic strips or sheets have an added disadvantage in that they do not always provide a high or uniform contact with the skin, in that the sheets do not always follow the contour of the body and thus only partial contact, and sometimes very low contact is achieved. Also the metal may have sharp edges which can cause injury. In many cases sweat is relied upon to provide a carrier to the skin can actually accumulate and form a barrier as can the presence of hair. It has also been found that the adhesives used to bond the active ingredients to the patch can irritate more sensitive skin types, rendering the use of patches impossible in some cases.

It is one object of the present invention to overcome the disadvantages of the above as well as to provide a more versatile and universal patch structure.

According to the present invention a patch structure for transdermal therapy

comprises at least one layer of sheet material having a plurality of particulate material on at least one surface thereof.

The sheet material provides a carrier for the particulate material but may also be an active ingredient itself. The carrier may be a pad of a foam or other elastomeric material. The sheet material may be made of any convenient material used in or suitable for skin contact, for example hypo-allergic material for prolonged use, and all or part of one surface of the sheet material may carry an adhesive for applying to the skin. The sheet material may be of more than one layer in that there is provided a first layer on which the particulate material is carried or embedded, and a second or subsequent layer carrying the first layer and adapted to overlie the skin. The sheet material may be any covenient shape, such as circular or oval or the like.

The particulate material may be of any suitable material including or incorporating one or any combination of the following materials; metallic, ceramic, gelatinous, or of soluble plastics, natural sponge, cellulose, or any suitable material capable of carrying a required substance for therapy. The particulate material may be formed from any combination of materials. Thus a combination of metallic, magnetic and ceramic particles, for example may be used to enhance performance or to create a variety of effects.

The particulate material may be in any convenient shape, such as spherical, or size, such as between 45 to 1000 micron. For example the particulate material may be of any shape both regular and irregular, symmetrical or non-symmetrical. Some shapes, such as cylinders may be bound or co-joined to form tufts. The particulate material may be solid, hollow or porous, and may itself be the active ingredient or act as a carrier for said ingredient. The particulate material may be arranged in any formation as suits the particular application. It will be seen that where certain shapes of material are used spaces will naturally form between. Alternatively the material can be arranged so that definite spaces are provided. It is an advantage that the spaces tend to fill with sweat enhancing contact with the skin.

The particulate material may be bonded to the sheet material using any standard adhesive. It will be seen that the particulate material may extend from the adhesive to ensure said adhesive has no or minimum contact with the skin. The adhesive may be applied as a layer or may be discrete. The bonding material may be absorbent or waterproof, and may itself carry an active ingredient.

Generally a patch having this structure will have on a single surface the area carrying the particulate material thereon together with an area bearing the adhesive for adhering to the skin. Alternatively, where the user has sensitive skin the patch carries no additional adhesive and is held on the skin by other means. One solution is to provide adhesive on the surface of the patch remote from the active ingredients so that the patch can be adhered inside clothing, or to the inside of a band such as a wristband or a waistband or the like. The need for adhesives can be reduced or eliminated by trapping the particulate material between a permeable layer of sheet material and the carrier material to ensure that the re can be no direct contact between the skin and the adhesive bonding the particulate material. It is a particular advantage of elongate particles arranged in tufts or in tuftlike array the skin can be kept free from the adhesive.

It is to be noted that the invention is not restricted to relatively small patches that are normally envisaged, but may be employed on a larger scale depending on the application or surface area.

The particulate material itself may be self-bonded where the active material is flexible or elastic such as an impregnated cellulose.

In one embodiment of the present invention a patch structure comprises a layer of sheet material carrying, on at least one area of one surface thereof, a plurality of spherical particles of zinc and of copper arranged in a formation so that the particles are in close proximity but may or not be touching. When placed on the skin, either by conventional adhesive or by other means described elsewhere very small electromagnetic impulses are

generated, useful in the treatment of skeletal or muscular pain, for example arthritis.

In another embodiment the particulate material is a ceramic of a size between 800 to 1000 micron and impregnated with an active ingredient, the particles are arranged in formation in one or more planes and bonded together and then adhered to the sheet material. It will be appreciated that by varying the manner in which the particles are bonded together the manner in which the active ingredient(s) is absorbed can be varied.

In one embodiment a size range of between 200-600 microns may be employed.

In another embodiment the particulate material is provided by spheres of copper, of 0.5mm diameter and arranged to surround in close formation a small magnet, or an array of magnetised particulate material, which arrangement may be bonded directly to the carrier or may be embedded in a flexible layer bonded to the carrier. The use of a magnet or magnetised particulate material assists in promoting the generation of electromagnetic impulse and/or current and/or magnetic field. Alternatively the particulate material material may comprise at least two different metals.

Any suitable magnet, whole or in particulate form may be used but preferably rare earth magnets, such as samarium or neodymium ion boron, are used. Such magnets are powerful for their size and thus much small magnets can used to the same effect. In one embodiment a neodymium ion boron magnet of a size 3mm across by 1mm deep and a strength of 2000 oersteds is preferred.

The magnet or magnetic particals are preferably coated with a suitable material, e.g. zinc or plastics.

In another embodiment of the present invention a plurality of layers of spherical granules of copper, of a size between 45 up to 1000 micron and covering an area of 30mm square. When the resulting arrangement is applied to the skin the sweat from the skin is

drawn up by the capillary action created between the granules which results in an improved circulation of the sweat. Hair on the skin can also be accommodated between the granules more readily. The arrangement may be gently massaged to provide or enhance pressure point stimulation by the granules on the skin. This arrangement may be used with a magnet as in other embodiments. The movement of copper particles in the magnetic field generates very small electric impulses.

In another embodiment porous copper spheres may be provided and can act a carrier for another active ingredient, or a catalyst for example.

Arrangements of these later embodiments can also provide a cushion or cushions to protect the wearer against injury from other components of the patch, such as a large magnet of the type described in GB Patent *1596314.*

The Invention will now be described by way of example with reference to the accompanying drawings in which:-

Figure 1 is an enlarged plan of a patch in accordance with one embodiment of the invention;

Figure 2 is a section of the line II-II of Figure 1; and

Figure 3 corresponds to Figure 1 but shows a patch in accordance with a further embodiment of the invention.

In Figures 1 and 2 a patch structure 10 for transdermal therapy comprises a layer of sheet material 11 carrying particulate material 12 of copper, held by an adhesive pad 13 in a ring formation about a zinc coated rare earth magnet 14. The sheet material 11 is provided with a further layer of adhesive 15 for application to the skin(not shown).

In the embodiment of Figure 3 the patch structure 10 is provided with a plurality of areas of zinc particles 16 and copper particles 17 arranged in formation so that the particle areas are in close proximity but do not touch, and surround a rare earth magnet 18. Again the sheet material carries an adhesive layer 15.

CLAIMS

1. A patch structure for transdermal therapy comprising at least one layer of sheet material having a plurality of particulate material on at least one surface thereof.

2. A patch structure for transdermal therapy as in Claim 1 wherein the sheet material provides a carrier for the particulate material and carries adhesive for applying the patch to the skin.

3. A patch structure for transdermal therapy as in Claim 2 wherein the carrier is a pad of a foam or other elastomeric material.

4. A patch structure for transdermal therapy as in Claims 1 or 2 wherein the sheet material is of more than one layer in that there is provided a first layer on which the particulate material is carried and a second layer carrying the first layer and adapted to overlie the skin.

5. A patch structure for transdermal therapy as in any one of the preceding Claims wherein the sheet material is of any convenient shape, such as circular or oval or the like.

6. A patch structure for transdermal therapy as in any preceding Claim wherein the particulate material includes or incorporates one or any combination of the following materials; metal, ceramics, gelatine, soluble plastics, natural sponge, cellulose or any suitable material capable of carrying a required substance for therapy.

7. A patch structure for transdermal therapy as in any preceding Claim wherein the particulate material is spherical.

8. A patch structure for transdermal therapy as in any preceding claim wherein the particulate material is of a size between 45 - 1000 microns.

9. A patch structure for transdermal therapy as in any one of Claims 1 - 5, and 7 wherein the particulate material is cylindrical in shape and bound or co-joined to form tufts.

10. A patch structure for transdermal therapy as in any preceding claim wherein the particulate material is hollow or porous.

11. A patch structure for transdermal therapy as in any one of claims 1- 7 wherein the particulate material is the active ingredient.

12. A patch structure for transdermal therapy as in any preceding claim wherein the particulate material acts a carrier for an active ingredient.

13. A patch structure for transdermal therapy as in any one of Claims 1 and 3 - 12 wherein the patch is not directly adhered to the skin.

14. A patch structure for transdermal therapy as in Claim 13 wherein the patch is adhered inside clothing or to the inside of a band such as a wrist band or the like.

15. A patch structure for transdermal therapy comprising a layer of sheet material carrying, on at least one area of one surface thereof, a plurality of spherical particles of zinc and copper arranged in a formation so that the particles are in close proximity but may or may not be touching.

16. A patch structure for transdermal therapy as in any one of claims 1 - 14 wherein the particulate material is a ceramic of a size between 800 - 1000 micron and impregnated with an active ingredient.

17. A patch structure for transdermal therapy as in any one of claims 1- 13 wherein he particulate material is of a size between 200 - 600 micron.

18. A patch structure for transdermal therapy as in any one of claims 1 - 14 wherein the particulate material is provided by spheres of copper of 0.5mm diameter and arranged to surround in close formation a small magnet, or array of magnetised particulate material.

19. A patch structure for transdermal therapy as in claim 18 wherein the particulate material comprises at least two different metals.

20. A patch structure for transdermal therapy as in claims 18 or 19 wherein the magnet or magnetised particulate material is provided by rare earth magnets.

21. A patch structure for transdermal therapy as in Claim 20 wherein the magnet is coated with zinc or plastics.

22. A patch structure for transdermal therapy comprising at least one layer of sheet material having a plurality of particulate material provided by layers of spherical granules of copper, of a size between 45 - 1000 micron and covering an area of 30mm square.

23. A patch structure for transdermal therapy as in any preceding Claim wherein there is provided a magnet or magnetised material.

24. A patch structure for transdermal therapy comprising at least one layer of sheet material having a plurality of particulate material provided by porous copper spheres acting as a carrier for another active ingredient.

25. A patch structure for transdermal therapy as claimed in any preceding claim wherein there are provided a cushion or cushions to protect a wearer against injury from any of the components of the patch structure.

The Patent Office

9

Application No:	GB 9609478.4	**Examiner:**	Gareth Griffiths
Claims searched:	1-21, 23 & 25	**Date of search:**	16 August 1996

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.O): A5R (RHFMP, RHAC, RHEC)

Int Cl (Ed.6): A61M 35/00, A61N 1/04, 1/30, 2/08

Other: Online Database: WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	EP0495743 A1	(BERTHELSON) whole document	1, 4, 5, 6, 8, 11, 13, 14, 17
X	EP0399765 A2	(ADVANCED POLYMER SYSTEMS) p.3 line 39 - p.4 line 10	1, 5, 6, 8, 10, 12, 14, 17
X	EP0036022 A1	(URAGAMI) whole document	1, 2, 5, 6, 8, 11, 14, 17, 23
X	WO95/06496 A1	(L.H.D.) fig.1 & abstract	1-6, 8, 10, 12, 14, 17
X	US5466465	(ROYDS) whole document	1-8, 11, 14, 17
X	US4067342	(BURTON) whole document	X: 1, 2, 5, 6, 23

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